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AUG 23 2002

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REMARKS

Claims 61-77 constitute the pending claims in the present application. Applicants cancel, without prejudice, claim 69. Applicants respectfully request reconsideration in view of the following remarks.

1. Applicants note with appreciation that the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114, and that Applicants' submission of March 13, 2002 has been entered.

2. Applicants enclose herewith appropriate documentation for compliance with the sequence requirements of 37 CFR 1.821 through 1.825.

3. The specification is objected to over certain informalities. Applicants' amendment to the specification is believed to obviate this objection.

5. Applicants note with appreciation that the rejection of claims 61-77 under 35 U.S.C. 112, first paragraph, has been withdrawn in view of Applicants' arguments.

6. Claims 61-77 are rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants traverse this rejection to the extent it is maintained in light of the amended claims.

The rejection appears to be based on three separate issues. Firstly, claims 62 and 72-75 are rejected for being directed to methods wherein agents are contacted with a cell having a patched loss of function phenotype. Applicants maintain the arguments of record, and contend that the specification specifically supports and contemplates the use of the present methods for examining cells characterized by mutations in other points in the hedgehog signaling pathway. Nevertheless, to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended the claims to explicitly point out the claimed methods. Applicants' amendments are not in acquiescence of the rejection, and Applicants' reserve the right to prosecute claims of similar or differing scope.

The remaining grounds for rejection allege that the specification fails to support the claimed subject matter, and thus the claims represent new matter. Applicants traverse these grounds of rejection to the extent that they are maintained in light of the amended claims.

Applicants direct the Examiner's attention to several pages of the specification which provide ample support for the full scope of the claimed subject matter (page 19, line 4 – page 22, line 23). One passage of specific note is found on page 20, lines 21-29.

“Other assays of interest detect agents that mimic patched function, such as repression of target gene transcription, transport of patched substrate compounds, etc. For example, an expression construct comprising a *patched* gene may be introduced into a cell line under conditions that allow expression. The level of patched activity is determined by a functional assay, as previously described. In one screening assay, candidate agents are added in combination with a Hh protein, and the ability to overcome Hh antagonism of *ptc* is detected. In another assay, the ability of candidate agents to enhance *ptc* function is determined. Alternatively, candidate agents are added to a cell that lacks functional *ptc*, and screened for the ability to reproduce *ptc* in a functional assay.”

Applicants contend that the specification provides specific support for a range of methods for detecting agents. Guided by the embodiments explicitly outlined in the specification, and standard methods in molecular biology well-known in the art, one of skill in the art would generally recognize that Applicants had possession of the claimed invention at the time the application was filed.

Additionally, Applicants' point out that in accordance with MPEP 2163.02, the standard for satisfying the written description requirement “is whether a claim defines an invention that is clearly conveyed to those of skill in the art at the time the application was filed.” However, the MPEP additionally reminds us that “[t]he subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.” (MPEP 2163.02). Accordingly, Applicants contend that the specification provides ample support to adequately describe the claimed subject matter.

In light of the specification, the advanced state of the art in molecular biology, and the MPEP, Applicants contend that the claimed methods satisfy the written description requirement. Reconsideration and withdrawal of the rejection are respectfully requested.

7. Claims 63-71, 76 and 77 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants traverse this rejection to the extent that it is maintained in light of the amended claims.

a. Claims 63-71, 76 and 77 are rejected because the second method step is allegedly unclear. Applicants contend that the claims are clear, and that the method simply reflect a standard practice of comparing cells under various conditions. Nevertheless, to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended the claims to improve their clarity. Applicants' amendments are not in acquiescence of the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Reconsideration and withdrawal are respectfully requested.

b. Claim 65 is rejected for allegedly failing to provide sufficient antecedent basis. Applicants have amended claim 65, as suggested by the Examiner. Applicants' amendments are believed to obviate the rejection.

8. Claims 61-63, 65, 68, 70, 72 and 74-77 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Li et al. Applicants traverse this rejection to the extent it is maintained in light of the amended claims.

Applicants contend that Li et al. fails to teach or suggest each and every limitation of the pending claims, and accordingly Li et al. fails to satisfy the criteria for anticipating the claimed invention. Li et al. neither teach nor suggest methods of identifying agents which decrease hedgehog signal transduction in cells characterized by a loss of function of a patched gene, as required by the pending claims. Reconsideration and withdrawal of the rejection are respectfully requested.

9. Claim 61 is rejected under 35 U.S.C. 102(a) as allegedly being anticipated by either of Noveen et al. or Hammerschmidt et al. Applicants traverse this rejection to the extent it is maintained in light of the amended claims.

Applicants contend that neither of the cited references teach or suggest each and every limitation of the pending claims, and thus these references fail to satisfy the criteria for

anticipating the claimed invention. Noveen et al. or Hammerschmidt et al. fail to teach or suggest methods of identifying agents which decrease hedgehog signal transduction in cells characterized by a loss of function of a patched gene, as required by the pending claims. Accordingly, reconsideration and withdrawal of the rejection are requested.

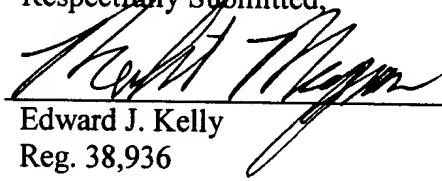
### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

Date: August 16, 2002

**Customer No: 28120**  
Docketing Specialist  
Ropes & Gray  
One International Place  
Boston, MA 02110

Respectfully Submitted,

  
Edward J. Kelly  
Reg. 38,936

42,852  
for EJK